

## **REMARKS**

Claims 1-23 are pending. Claims 1-23 are under examination.

## **PRIORITY**

Applicant acknowledges the Examiner's comments relating to the issue of priority claiming found at pages 2-3 of the Office Action. It is kindly submitted that a Petition under 37 C.F.R. § 1.78 to accept an unintentionally delayed claim of priority is being filed in this case under separate cover.

## **Rejections Under 35 U.S.C. § 102(b)**

Claims 1-6, 9-11, 14-18, and 21-23 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,231,608 ("Stone"). Applicant respectfully traverses for the following reasons.

Dr. Stone pioneered the field of xenotransplantation by discovering methods for processing xenogenic materials to obtain substantially-non immunogenic preparations suitable for implantation into humans. In fact, it is submitted that the approaches set forth in Stone and in the underlying Application are very different contributions providing compositions and treatment modalities for significantly different tissues and defects.

The present invention provides a substantially non-immunogenic collagen-containing material for injection into a human, for example, for soft tissue augmentation. The Examiner is kindly directed to paragraph [0016] of the instant Application where it is provided that the term "soft tissue augmentation" means,

*"dermal tissue augmentation; filling of lines, folds, wrinkles, minor facial depressions, cleft lips and the like, especially in the face and neck; correction*

*of minor deformities due to aging or disease, including in the hands and feet, fingers and toes; augmentation of the vocal cords or glottis to rehabilitate speech; dermal filling of sleep lines and expression lines; replacement of dermal and subcutaneous tissue lost due to aging; lip augmentation; filling of crow's feet and the orbital groove around the eye; breast augmentation; chin augmentation; augmentation of the cheek and/or nose; filling of indentations in the soft tissue, dermal or subcutaneous, due to, e.g., overzealous liposuction or other trauma; filling of acne or traumatic scars and rhytids; filling of nasolabial lines, nasoglabellar lines and infraoral lines."*

Stone relates to articles of manufacture comprising substantially non-immunogenic soft and bone tissue xenografts for implantation into humans. Specifically, Stone relates to the field of treatment of defective human knee joints, heart valves, and bone and in particular, to replacement and repair of defective or damaged human knee joints, heart valves, and bone. Notably, at Col. 1, line 21, Stone provides as follows:

*"[t]he term "soft tissue", as used herein, refers to cartilaginous structures, such as meniscus and articular cartilage; ligaments, such as anterior cruciate ligaments; tendons; and heart valves."*

The passage relied upon by the Examiner at Col. 15, lines 51 *et seq.* provides in full as follows,

*"[p]rior to implantation, the soft or bone tissue xenograft of the invention may be treated with limited digestion by proteolytic enzymes such as ficin or trypsin to increase tissue flexibility, or coated with anticalcification agents, antithrombotic coatings, antibiotics, growth factors, or other drugs which may enhance the incorporation of the xenograft into the recipient joint. The soft tissue xenograft of the invention may be further sterilized using known methods, for example, with additional glutaraldehyde or formaldehyde treatment, ethylene oxide sterilization, propylene oxide sterilization, or the like." (bold and underline added for emphasis).*

Hence, Stone contemplates bone and soft tissue xenotransplants and does not describe, nor it teaches or suggests injectable collagen. In fact, Stone describes treatment of soft

and bone tissue “with limited digestion by proteolytic enzymes” (see paragraph reproduced *supra*). Such limited digestion is not meant to obtain injectable collagen, but is suggested for the mere purpose of increasing tissue flexibility, as expressly stated.

It is further noted, that because Stone does not describe, teach or suggest injectable collagen, Stone also does not address methods to inject collagen at all.

On the contrary, the instant Application provides ample disclosure relating to the very issue. Paragraphs [0069]-[0076] of the instant Application expressly address the specific issue of providing collagen-containing materials which have been digested to the extent necessary to be in the form of “*liquid, colloid, semi-solid, suspended particulate, gel, paste, combinations thereof, and the like*”). In these passages, Applicant also contemplates specific requirements to meet the exigencies associated with the delivery of a preparation which is, unlike the compositions of Stone, not solid but in a form amenable for injection. Hence, for example Stone addresses the issue of adding lubricant materials to enhance injectability through a narrow diameter needle. Similarly, the instant Application contemplates delivery via a polymeric catheter component such as a cytoscope.

For these reasons, it is submitted that the rejected claims are novel in light of Stone. Accordingly, reconsideration and withdrawal of these rejections is kindly requested in light of the foregoing remarks.

#### **Rejections Under 35 U.S.C. § 103(a)**

Claims 7-8, 12-13 and 19-20 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Stone and in further view of U.S. Patent No. 5,989,498 (“Odland”).

For the reasons discussed above, Stone does not teach or suggest the compositions and methods according to the instant invention.

Odland purportedly relates to methods of sterilizing biological materials using electron-beam sterilization methods. It is submitted that Odland does not cure the deficiencies of Stone.

For these reasons, it is submitted that the rejected claims are non-obvious in light of Stone in further view of Odland. Accordingly, reconsideration and withdrawal of these rejections is kindly requested in light of the foregoing remarks.

### CONCLUSION

In light of the amendments and remarks herein, Applicant submits that the claims are now in condition for allowance and respectfully requests a notice to this effect. The Examiner is invited to contact the undersigned if there are any questions.

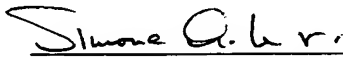
A Request for a Three (3) Month Extension of Time, up to and including March 22, 2005 is included herewith. Pursuant to 37 C.F.R. § 1.136(a)(2), the Examiner is authorized to charge any fee under 37 C.F.R. § 1.17 applicable in this instant, as well as in future communications, to Deposit Account 50-1133.

<< PLEASE SEE NEXT PAGE >>

*Kevin R. Stone*  
*U.S.S.N. 10/722,869*  
*Response to Office Action Pursuant to 37 C.F.R. § 1.111*  
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Furthermore, such authorization should be treated in any concurrent or future reply requiring a petition for an extension of time under § 1.136 for its timely submission, as constructively incorporating a petition for extension of time for the appropriate length of time pursuant 37 C.F.R. § 1.136(a)(3) regardless of whether a separate petition is included.

Respectfully submitted,

  
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